

ANTIMICROBIAL AGENT DELIVERY SYSTEM

INVENTORS:

Kristin Feeley
Ray Lareau

PREPARED BY

KENYON & KENYON

1500 K Street, NW
Washington, DC 20005
(202) 220-4200

ANTIMICROBIAL AGENT DELIVERY SYSTEM

Field Of The Invention

[0001] Embodiments of the present invention are directed to an improved system and
5 method for delivering antimicrobial agents into catheters.

Background

[0002] Catheters have become widely used in modern medicine to provide one or
more lumens into a patient's body through which a wide variety of procedures may be
10 performed or fluids may be introduced or removed from the patient. Examples include
catheters lumens through which minimally-invasive surgical procedures, such as angioplasty
balloon deployment or tissue resection, may be performed, catheters for introducing
therapeutic substances at desired sites within the patient, catheters for the removal and/or
replacement of fluids, such as blood removal and replacement during hemodialysis, and
15 catheters associated with activation of mechanisms for medical devices, such as activation of
control cables or application of pneumatic pressure to inflate balloons or expand stents at
target locations within the patient.

[0003] Inherent with the use of medical devices placed within a patient is the risk of
infection from the medical device. While great strides have been made in the last century in
20 preventing infection during surgical procedures, this risk has not been entirely eliminated.
For example, it has been estimated that central venous catheters account for more than 90
percent of all nosocomial catheter-related blood stream infections.

[0004] In the case of central venous catheters, characteristically, at an infected site a
large number of microorganisms are adherent on the catheter, where there is an interaction
25 between the pathogen and the catheter microsurface. Once so infected, the microorganisms
adhere to the catheter and rapidly become encased in a polysaccharide matrix or biofilm
which protects the microorganisms from the natural defenses of the host. While there have
been recent developments of central venous catheters to attempt to reduce the incidence of
nosocomial catheter-based infections, such as the use of catheters with liquid chlorhexidine

and silver sulfadiazine, or with a combination of minocycline and rifampin, such infections have yet to be eliminated.

[0005] The use of antimicrobial agent-bearing intervention devices has been proposed for the management of nosocomial blood stream infections. Antimicrobial agents such as povidone-iodine, chlorhexidine, polymicrobial gel, isopropyl alcohol and hydrogen peroxide have long been used in medical practice as disinfectants, with iodine having been discovered to be one of the most effective antiseptics in the 1870s. Recently, iodine-bearing formulations have been developed that may be applied to, or incorporated into, medical devices to provide controlled in-situ release of iodine as an antimicrobial agent. One potential application of such formulations is an iodine-bearing polymeric rod that can be inserted into a catheter, where the rod delivers iodine to the catheter in order to manage catheter-based nosocomial bloodstream infections. In this example, an iodine-bearing polymeric intervention device is placed within an indwelling catheter. As a result, elemental iodine may be released to diffuse to the catheter wall, and if the catheter wall material is semi-permeable, to diffuse through the catheter wall to the exterior surface of the catheter. Thus, the iodine may be made available to eliminate micro-organisms on both the inner and outer micro-surfaces of the catheter.

[0006] Notwithstanding the advantages in catheter-based nosocomial blood stream infection management offered by the use of an iodine-bearing polymeric intervention device, installation or delivery of the device into the catheter presents a number of challenges. For example, during insertion into the catheter, it is highly desirable for the intervention device to remain sterile and, therefore, out of direct contact with equipment, hands, and any other non-sterile surfaces. In addition, due to the relatively low column strength of rod implementations of the intervention devices, control over the rod can be less than desired. There is therefore a need for a delivery system that provides sterility by reducing direct handling of antimicrobial agent-bearing intervention devices. There is also a need for a delivery system that enhances control over the insertion of the intervention device during insertion into the catheter lumen.

Summary Of The Invention

[0007] In accordance with certain embodiments of the invention, systems and methods of delivering antimicrobial agent-bearing intervention devices are provided for reduced handling and improved control of the intervention device.

5 [0008] In one embodiment, an antimicrobial agent delivery system includes an antimicrobial agent-bearing intervention device and a delivery tube containing the intervention device. The delivery tube facilitates manipulation of the intervention device.

[0009] In another embodiment of the invention, an antimicrobial agent delivery system includes an antimicrobial agent-bearing rod, a delivery tube, and a hub. The delivery
10 tube contains the rod, and the delivery tube facilitates manipulation of the rod. The hub is coupled to the rod, and movement of the hub ejects the rod from the delivery tube. The delivery tube may have a longitudinal partition and a hub opening, where the hub opening provides external access to the hub and the longitudinal partition guides the hub longitudinally. The hub is optionally disposed within the delivery tube. An extension arm
15 may be connected to the hub and may extend through the hub opening. If desired, the extension arm may be connected to the hub at a tapered connection point, where the tapered connection point enables removal of the extension arm from the hub after ejection of the rod from the delivery tube.

[0010] In yet another embodiment, a method of fabricating an antimicrobial agent
20 delivery system provides for coupling a hub to an antimicrobial agent-bearing rod. A longitudinal partition and a hub opening are formed in a delivery tube. The method further provides for disposing the rod within the delivery tube, where the hub opening provides external access to the catheter hub.

25 **Brief Description Of The Drawings**

[0011] The foregoing and further objects, features and advantages of the invention will become apparent from the following detailed description with reference to the accompanying drawings, wherein like numerals are used to represent like elements and wherein:

30 [0012] Fig. 1A is a side view of an example a delivery tube according to one embodiment of the invention;

[0013] Fig. 1B is a side view of an example of an antimicrobial agent delivery system before ejection according to one embodiment of the invention;

[0014] Fig. 1C is a side view of an example of an antimicrobial agent delivery system during ejection according to one embodiment of the invention;

5 [0015] Fig. 2 is a side view of an example of antimicrobial agent delivery system according to another embodiment of the invention;

[0016] Fig 3 is a side view of an example of an antimicrobial agent delivery system having a multiple lumen geometry according to another embodiment of the invention;

10 [0017] Fig. 4 is a side view of an example of an antimicrobial agent delivery system having a plunger according to another embodiment of the invention;

[0018] Fig. 5A is a side view of an example of a tapered connection point between a hub and an extension arm according to an embodiment of the invention;

[0019] Fig. 5B is an end view of an alternative example of a tapered connection point between a hub and an extension arm according to another embodiment of the invention;

15 [0020] Fig. 5C is a side view of a example of a non-tapered connection between a hub and an extension arm according to another embodiment of the invention;

[0021] Fig. 6A is an end view of an example of a hub having surfaces defining one or more apertures that enable fluid transfer according to an embodiment of the invention;

20 [0022] Fig. 6B is an end view of another example of a hub having surfaces defining one or more apertures that enable fluid transfer according to another embodiment of the invention;

[0023] Figs. 7A and 7B are cut-away views of an example of a valve according to an embodiment of the invention; and

25 [0024] Fig. 8 is a flowchart of an example of a method of fabricating an antimicrobial agent delivery system according to one embodiment of the invention.

Detailed Description

[0025] Some possible embodiments of the invention are hereafter described. One embodiment of the present invention is illustrated in Figs. 1A-1C.

30 [0026] Fig. 1A shows a delivery tube 14. The delivery tube 14 has a longitudinal partition, in this case a perforation 20, and a hub opening 18. The longitudinal partition may

be perforated, as shown, pre-scored, a continuous slit, or any other configuration that enables the functioning as described below.

[0027] Figs. 1B and 1C show an antimicrobial agent delivery system 10. The antimicrobial agent delivery system 10 includes an antimicrobial agent-bearing intervention device, such as rod 12, and the delivery tube 14. The antimicrobial agent-bearing intervention device may have any suitable geometry. For example, it may be a tube or have an irregular shape, etc. Similarly, the delivery tube may have any suitable geometry. For example, it may have a cross-sectional geometry that is similar to or different from the cross-sectional geometry of the intervention device.

[0028] In the assembled configuration shown in Fig. 1A, the antimicrobial agent-bearing intervention device is a rod 12 is disposed within the delivery tube 14. The delivery tube 14 facilitates manipulation of the rod 12. That is, because the rod 12 is in the delivery tube 14, the rod 12 can be moved by simply grasping the delivery tube 14, without the need to handle the rod 12 itself.

[0029] A hub 16 is coupled to the rod 12. In this illustrated embodiment, an extension arm 22 is coupled to the hub 16. In the assembled configuration shown in Fig. 1A, the extension arm 22 extends through the hub opening 18.

[0030] The operator can eject the rod 12 from the tube 14 by longitudinally moving the hub 16 via extension arm 22. The hub opening 18 provides external access to the hub 16, and the perforation 20 guides the hub 16 longitudinally. Longitudinal movement of the hub 16 results in ejection of the rod 12 from the delivery tube 14. Thus, without touching the rod 12, the rod 12 can be removed from the delivery tube 14 for use with a catheter.

[0031] Fig. 5A shows an embodiment in which the extension arm 22a is tapered toward the point where it connects with the hub 16a, such that the extension arm 22a and the hub 16a have a tapered connection point 24a. In Figure 5A, the width of the extension arm 22a is tapered. Figure 5B shows an alternative embodiment in which the thickness of the extension arm 22b is tapered toward the point where it connects with the hub 16b, such that the extension arm 22b and the hub 16b have a tapered connection point 24b. The tapered connection point 24a or 24b enables removal of the extension arm from the hub after ejection of the rod from the delivery tube 14 (Figs. 1A-1C). The tapered connection may have other suitable configurations, or other types of geometries or structures may be used, to facilitate

separation of the extension arm from the hub, if desired. Of course, the extension arm need not be tapered, as shown in Fig. 5C, leaving a non-tapered connection point 24.

[0032] Turning now to Fig. 2, another embodiment of an antimicrobial agent delivery system is shown. In this embodiment, a delivery system 31 includes an antimicrobial agent-bearing rod 26 and a delivery tube 32. The antimicrobial agent-bearing rod 26 has a flex point 28. A hub 30 is connected to the end of the antimicrobial agent-bearing rod and is disposed outside the delivery tube 32. It should be noted that disposing the hub 30 outside the delivery tube 32 enables the delivery tube 32 to be reduced in size considerably. It should also be noted that the illustrated delivery tube 32 has a longitudinal partition, where the partition is a continuous slit 34 rather than a perforation. In such a case, it may be advantageous to structure the material of the delivery tube to enable the slit 34 to be self-sealing. One such material would be thermoplastic polyurethane (TPU), which has a low durometer characteristic to provide a desired level of “tackiness” on the surfaces that define the slit 34. The resulting slit 34 would provide a dynamic seal that can be broken and immediately re-sealed as the rod 26 is advanced through the delivery system 31.

[0033] Fig. 3 shows another alternative embodiment of an antimicrobial agent delivery system in which a delivery tube 36 has a multiple lumen geometry. The multiple lumen geometry is defined by a first tube 38 and a second tube 40. An antimicrobial agent-bearing rod 42 is disposed within the first tube 38. The rod 42 may be connected to a hub 44 that is disposed within the second tube 40. Alternatively, the rod 42 may be connected to a hub disposed within the first tube 38, and the hub may be connected to an extension arm that extends into the second tube 40. The rod 42 connects to the hub 44 (or the extension arm projects) through a longitudinal partition 46 defined by surfaces in a wall 48 that connects the first tube 38 to the second tube 40. The hub and rod can be advanced through the delivery tube 36 by manipulating an extension arm (not shown) along a longitudinal partition formed in the second tube 44, by manipulating a plunger (not shown) into second tube 40 to act on the extension arm or hub, or by any other suitable actuation structure.

[0034] Turning now to Fig. 4, another embodiment of an antimicrobial agent delivery system is shown. In this embodiment, a delivery system 50 includes a plunger 52 extending out of an end of a delivery tube 54, where the plunger 52 is in contact with a hub 56. The hub

56 is attached to an antimicrobial agent-bearing rod 58. The delivery tube 54 has openings at both ends to accommodate the longitudinal movement of the plunger 52 as well as the rod 58. It should be noted that this delivery system 50 does not require a longitudinal partition.

[0035] Turning now to Fig. 6A, an end view of a hub is shown. The illustrated hub has surfaces defining one or more apertures 60a that enable fluid transfer through the hub while the antimicrobial agent-bearing rod is installed in a catheter (not shown). Fig. 6B shows another possible configuration of apertures 60b. With the apertures, the hub enables flushing and aspiration to take place around the rod. The apertures can be readily included in hub 16 (Figs. 1A-1C), hub 30 (Figs. 2), hub 44 (Fig. 3), and hub 56 (Fig. 4).

[0036] The outer surface of the above-described delivery tubes can include materials such as polyether block amide (PEBA), polyethylene, thermoplastic polyurethane (TPU), polyester elastomer, ionomer and thermoplastic vulcanizate to provide a relatively high surface texture. The result would be improved ergonomics and enhanced control. It should also be noted that the inner surface of the delivery tubes can include materials that are non-permeable to the particular antimicrobial agent being used. For example, in the case of iodine, the inner surface of the delivery tube may include PET.

[0037] Figs. 7A and 7B show a valve 72 that can be incorporated into an anti-microbial agent delivery system such as any of the systems discussed above. Valve 72 is coupled to an open end of a delivery tube 74, where the delivery tube 74 contains a hub 76 and rod 78. The valve 72 attaches to the hub 76 and detaches from the delivery tube 74 when ejection of the rod 78 is complete. The valve 72 attached to the hub 76 as shown in Fig. 7B enables the flow of fluid to and from a catheter (not shown) to be restricted as desired.

[0038] Turning now to Fig. 8, the method 62 of fabricating an antimicrobial agent delivery system is shown. Specifically, step 64 provides for coupling a hub to an antimicrobial agent-bearing rod. Step 66 provides for extruding a delivery tube. Step 68 provides for forming a longitudinal partition and a hub opening in the delivery tube. Step 70 provides for disposing the rod within the delivery tube, where the hub opening provides external access to the hub. It should be noted that method 62 may further include the process of coupling an external arm to the hub, in which case the step of disposing the rod within the delivery tube would include having the extension arm extend through the hub opening. Alternatively, the rod may have a flex point, where the hub is disposed outside the delivery

tube. It should also be noted that a wide variety of cutting systems, such as a laser cutting system or a mechanical cutting system, can be used to form the longitudinal partition and the hub opening at step 68. Also, step 64 may come after steps 66 or 68.

5 **[0039]** While the invention has been described with reference to what are presently
considered to be preferred embodiments thereof, it is to be understood that the invention is
not limited to the disclosed embodiments or constructions. On the contrary, the protection
sought for the invention as defined in the appended claims is intended to cover various
modifications and equivalent arrangements. In addition, while the various elements of the
disclosed invention are described and/or shown in various combinations and configurations,
10 which are exemplary, other combinations and configurations, including more, less or only a
single embodiment, are also within the spirit and scope of the present invention.